



SEP 11 1996

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510(k) Summary of Safety and Effectiveness
(in Accordance with SMDA of 1990)

Aesculap Endoscopic Clip Appliers
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Product Name

Trade Name: Endoscopic Clip Appliers
Common Name: Endoscopic Instruments
Classification Name: Endoscope and Accessories

Predicate Device

Aesculap's Endoscopic Clip Appliers with disposable clip magazine represents a modification to existing devices. The modified devices are compared to their predecessors, which were previously cleared in Aesculap's 510(k)'s. The modified Endoscopic Clip Appliers with disposable clip magazine are also compared to endoscopic clip appliers and implantable clips by Baxter, Ethicon, Horizon Surgical, and U.S. Surgical.

Device Description

Aesculap's Endoscopic Clip Appliers (PL506R, PL508R) are reusable stainless steel instruments 10mm in diameter and ranging in length from 260mm to 370mm. They are designed for use with a disposable clip magazine which attaches to the shaft of the clip applier. The clip magazine cartridge holds 8 titanium clips which can be applied one at a time. The instrument handle has a control lever for supplying the clips and a separate control lever for closing the clips. The design enables the surgeon to apply several clips without the need for withdrawing and reinserting the clip applier each time.

Like Aesculap's Modular Endoscopic Instruments, these clip appliers can be disassembled for cleaning, disinfection and sterilization. The handle can be removed, allowing the shaft of the instrument to be disassembled into three separate pieces.

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Intended Use

The devices presented in this submission are intended for use in endoscopic surgery for ligating and marking vessels and tubular structures.

Summary of Technological Characteristic

Aesculap's Endoscopic Clip Appliers represent no change in technological characteristics, only modifications to instrument design.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Endoscopic Clip Appliers and disposable clip magazine will be manufactruered in accordance with ISO and German Din Standards. Furthermore, Aesculap AG has received ISO 9001 certification.

Substantial Equivalence

Aesculap believes that the Endoscopic Clip Appliers presented in this submission are substantially equivalent in design, function, and intended use to the presented devices from Baxter, Ethicon, Horizon Surgical, and U.S. Surgical.